

**IN THE DRAWINGS:**

**Please replace the drawing sheets of record with the attached corrected drawing sheets.**

## **REMARKS**

In the Office Action dated June 3, 2005, claims 36-51 are pending and under consideration. The Examiner has objected to the Amendment filed on July 11, 2003. The Examiner has also objected to Applicants' claim for foreign priority. The application has been objected to for certain informalities. Claims 36-51 are rejected under 35 U.S.C. §112, second paragraph. Claims 36, 38-46 and 48-51 are rejected under 35 U.S. C. §112, first paragraph, for lacking enabling support and adequate written description. Claims 36, 38, 41-42, 45-48 and 51 are rejected under 35 U.S. C. §102(b) as allegedly anticipated by Abrams et al. (U.S. Patent 5,041,381).

This Response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

The Examiner has objected to the Amendment filed on July 11, 2003, which corrected certain errors in the sequences of SEQ ID NO: 1 and SEQ ID NO: 2 (representing murine sequences). The Examiner indicates that the Amendment did not disclose which part of the sequences was changed and where the changes found specific support in the specification.

Applicants respectfully submit that the Sequence Listing originally filed in the present application indicates that the nucleotide sequence of SEQ ID NO: 1 encodes a protein of 426 amino acids, with unknown codons "XXX" at amino acid positions 21 and 194. SEQ ID NO: 2 represents the amino acid sequence encoded by SEQ ID NO: 1, and contains unknown amino acid "Xaa" at position 21 and 194. Applicants respectfully submit that the inclusion of "XXX" in SEQ ID NO: 1 and "Xaa" in SEQ ID NO: 2 are clerical errors and should have been deleted. The

correct nucleotide and amino acid sequences are set forth in Figure 1 as originally filed, i.e., the nucleotide sequence consists of 1680 bp and encodes a protein of 424 amino acids. By way of the substitute Sequence Listing filed on July 11, 2003, Applicants have deleted the XXX's in SEQ ID NO: 1 and the Xaa's in SEQ ID NO: 2. No new matter is introduced by the substitute Sequence Listing.

The Examiner has also objected to Applicants' claim for foreign priority, alleging that Applicants have not submitted certified copies of the foreign priority applications.

Applicants respectfully submit that certified copies of the foreign priority applications were already filed in the parent case, Serial No. 09/051,843, on March 21, 2003. Accordingly, the objection to the foreign priority claim is overcome. Withdrawal of the objection is therefore respectfully requested.

The application has been objected to for an incorrect reference to the filing date of the parent case, Serial No. 09/051,843.

In response, Applicants have amended the cross-reference section to include the correct filing date of Serial No. 09/051,843. As such, the objection to the specification is overcome and withdrawal thereof is respectfully requested.

The application has also been objected to, because the labeling of the Figures does not match the description in the specification.

Applicants respectfully submit copies of the drawings with the correct drawing labels, which match the description of the drawings in the specification. Withdrawal of the objection to the drawings is therefore respectfully requested.

Furthermore, the Examiner has indicated that the application fails to fully comply with the sequence rules set forth in 37 C.F.R. §1.821. Specifically, the Examiner states that the sequence in Figure 6 and the amino acid sequence on page 37 are not identified by the corresponding sequence identifiers.

Applicants respectfully submit that Figure 6 does not contain any sequence. What the Examiner apparently believes to be at the bottom of Figure 6 is in fact Figure 10. The sequence identifiers corresponding to the sequences as set forth in Figure 10 have been added to the description of Figure 10 by way of the Amendment filed on July 11, 2003. Applicants have also amended the specification to include the sequence identifier corresponding to the amino acid sequence on page 37. Accordingly, Applicants respectfully submit that the application is in compliance with the sequence rules set forth in 37 C.F.R. §1.821.

Claims 36-51 are rejected under 35 U.S.C. §112, second paragraph. In particular, the Examiner has objected to the language of claims 36, 38, 41, and 44-51. Claims 37, 42 and 43 are rejected for depending upon an indefinite base claim.

More specifically, the Examiner considers claim 36 to be indefinite allegedly because the claim does not set forth any structural limitations of the claimed polypeptide that renders the polypeptide capable of binding human IL-13 and/or human IL-4.

Applicants respectfully submit that claim 36 has been canceled without prejudice, rendering the rejection thereof moot.

The Examiner also considers claim 38 to be indefinite for reciting the term "derivative".

Applicants observe that the term "derivative" is defined on page 7, lines 2-13 of the specification. On page 7, line 2, the specification states that derivatives include "parts, fragments, portions, homologues, hybrids or analogues thereof". Applicants have amended claim 38 to replace the term "derivative" with the recitation "part or fragment", which is fully supported by the specification. No new matter is introduced. In addition, Applicants observe that Example 6 of the specification (page 37 and Figure 1) defines the various domains of murine NR4 including a signal sequence, an extracellular domain, a transmembrane domain, and a cytoplasmic domain. Example 11 (pages 39-40) discloses that SEQ ID NO: 4 is the human homolog of murine NR4 with 75% similarity at the amino acid level; and Figure 7 aligns the human sequence with the murine sequence. In view of the disclosure in the specification, the term "part or fragment" of SEQ ID NO: 4, as presently recited in claim 38, is clear to those skilled in the art, and is understood to include, for example, an extracellular domain.

The Examiner has not explained why claims 39-40 are also included in this rejection. Applicants respectfully submit that claims 39-40 are not indefinite.

The Examiner has also objected to claims 41, 44, and 45 as indefinite, allegedly because of the recitations of "soluble form", "mature form" and "recombinant form".

Applicants respectfully submit that these terms are well understood by those skilled in the art in view of the instant disclosure. For example, the specification exemplifies a "soluble form" of murine NR4, which includes the extracellular part of murine NR4 and does not include a transmembrane segment. See page 40 of the specification. The term "mature form" is well understood by those skilled in the art to represent the portion of a protein after the signal sequence has been cleaved. See, e.g., the description of Figure 7 on page 32. The term

"recombinant form" is also understood by those skilled in the art to mean that the isolated polypeptide is recombinantly produced, as opposed to the polypeptide produced by other means.

With respect to claims 46-50, the Examiner alleges that it is not clear what the claimed composition comprises in addition to the recited polypeptide. Applicants have amended these claims to include "a pharmaceutically acceptable carrier". Support for this amendment is found in the specification, e.g., page 30, lines 27-29.

As to claim 51, the Examiner objects to the term "carrier". Applicants have canceled this claim, rendering the rejection thereof moot.

In view of the foregoing, it is respectfully submitted that the rejection of claims 36-51 under 35 U.S.C. §112, second paragraph, is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claims 36, 38-46 and 48-51 are rejected under 35 U.S. C. §112, first paragraph, for allegedly lacking enabling support. In particular, the Examiner contends that the claims encompass derivatives of SEQ ID NO: 4 having undefined structure and function, and that any random modification of SEQ ID NO: 4 could adversely alter the biological function of the protein.

In the first instance, it is unclear to Applicants why claims 39-40 are included in the rejection. These claims recite specific fragments of SEQ ID NO: 4, which those skilled in the art clearly can make and use without undue experimentation.

Further, Applicants respectfully submit that independent claim 38 has been amended to replace the term "derivative" with the recitation "part or fragment". As submitted above, the specification teaches various domains of murine NR4, including a signal sequence, an

extracellular domain, a transmembrane domain, and a cytoplasmic domain (page 37 and Figure 1). The specification also discloses that SEQ ID NO: 4 is the human homolog of murine NR4 with 75% similarity at the amino acid level, and aligns the human and murine sequences in Figure 7. Thus, in view of the disclosure in the specification, those skilled in the art would readily identify the corresponding domains or parts of SEQ ID NO: 4 and the activities/functions associated with such domains or parts, without undue experimentation. Accordingly, Applicants respectfully submit that the polypeptides, as presently claimed, are fully enabled by the specification. Withdrawal of the enablement rejection under 35 U.S. C. §112, first paragraph, is respectfully requested.

Claims 36, 38-46 and 48-51 are rejected under 35 U.S. C. §112, first paragraph, for allegedly lacking adequate written description. Essentially, the Examiner contends that the specification only describes SEQ ID NO: 4, but not the genus of proteins encompassed by the claims.

Applicants again direct the Examiner's attention to independent claim 38, which has been amended to replace the term "derivative" with the recitation "part or fragment". Applicants respectfully submit that in addition to the full-length protein as set forth in SEQ ID NO: 4, the specification describes the various portions and domains of murine NR4, and aligns the highly homologous human sequence (SEQ ID NO: 4) with the murine sequence in Figure 7. Therefore, the specification, at least implicitly, describes portions and fragments of SEQ ID NO: 4, which is certainly sufficient for one skilled in the art. Accordingly, Applicants respectfully submit that the polypeptides, as presently claimed, are adequately described in the specification. Withdrawal of the written description rejection under 35 U.S. C. §112, first paragraph, is respectfully requested.

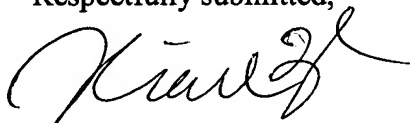
Claims 36, 38, 41-42, 45-48 and 51 are rejected under 35 U.S. C. §102(b) as allegedly anticipated by Abrams et al. (U.S. Patent 5,041,381).

Abrams et al. merely disclose an antibody that binds IL-4. The Examiner's rejection is based on an improper interpretation of claims 36 and 38. The Examiner contends that since the antibody disclosed by Abrams et al. has at least one amino acid in common with the polypeptide of SEQ ID NO: 4, the antibody is considered a "derivative" of the polypeptide as set forth in SEQ ID NO: 4. Therefore, the Examiner concludes that the antibody and compositions disclosed by Abrams et al. meet the limitations of claims 36, 38, 41-42, 45-48 and 51.

It is respectfully submitted that the foregoing amendment has obviated the rejection based on Abrams et al. Specifically, the term "derivative" has been replaced with "part or fragment" of SEQ ID NO: 4. Clearly, those skilled in the art understand that a "part or fragment" of SEQ ID NO: 4 does not include merely a single amino acid. Withdrawal of the rejection is therefore respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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